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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,816	05/23/2001	Paulo LaColla	06171.105027 NOV 1006	8968
20786	7590	10/01/2003		
KING & SPALDING 191 PEACHTREE STREET, N.E. ATLANTA, GA 30303-1763				
EXAMINER MCINTOSH III, TRAVISS C				
ART UNIT		PAPER NUMBER		
1623				

DATE MAILED: 10/01/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary

Application No.

09/863,816

Applicant(s)

LACOLLA ET AL.

Examiner

Traviss C McIntosh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 100-102, 131-141 and 145-181 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 100-102, 131-141 and 145-181 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.

- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)

- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8,13.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.

- 5) ☐ Notice of Informal Patent Application (PTO-152)

- 6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed August 27, 2003 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 1-99, 103-130, 142-144 have been cancelled.

Claims 100-102, 131-137, 141, 145-154 have been amended.

Claims 155-181 have been added.

An action on the merits of claims 100-102, 131-141, and 145-181 is contained herein below.

Election/Restrictions

Applicant's election without traverse of species XVII in Paper No. 12 is acknowledged.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Furthermore, document BA of the IDS submitted February 25, 2002 has not been considered as this was received in illegible form. The examiner requests that applicants resubmit the reference so it can be considered.

Specification

The disclosure is objected to because of the following informalities: table 12 does not define what is intended by "***", but rather defines "*" two times.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 100-102, 131-141, and 145-181 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

All of the independent claims 100-102, 145-150, and 155 are drawn to a method of treating a flavivirus or pestivirus comprising administering various compounds, however, the claims do not recite a host or an appropriate recipient of the active agent or compound. The claims are indefinite wherein they recite a method of treatment comprising administering a compound wherein there is nothing stated about who the compound is administered to. Adding "to a host in need thereof" would be seen to obviate the rejection instantly at hand.

Claims 137 and 158 provide the limitation that the compound administered is "in the form of a dosage unit". It is unclear how this recitation further limits the claims from which these depend. Any amount of the compounds which are administered is seen to be "in the form of a dosage unit", therefore, the compound is already in a "dosage unit" as set forth in the independent claims from which these depend.

Claim 155 is indefinite wherein the claim is not set forth in a way which provides proper Markush language. Specifically, the variables set forth to define R^4 require an "or" to be inserted between the last two variables of the group, that is, "... -N(lower alkyl)₂, -N(acyl)₂" should read "... -N(lower alkyl)₂, **or** -N(acyl)₂" or "selected from the group consisting of ... "... -N(lower alkyl)₂, **and** -N(acyl)₂". Likewise, the variables defining R^5 and R^6 require the same correction.

Claim 155 includes the limitation of "the phenyl group is optionally **substituted** with one or more **substituents**..." in the Markush group defining R^1 . In the absence of the identity of moieties which are intended to be substituted, thus modifying an art recognized chemical core, described structurally or by chemical name, the identity of "substituted" would be difficult to ascertain. In the absence of said moieties, the claims containing the term "substituted" are not described sufficiently to distinctly point out that which applicant intends as the invention.

Claims 162 and 179 provide the limitation "wherein the compound is in **substantially pure form**". It is noted that although the specification defines "substantially pure", the examiner reads the claims in light of the specification, but does not read these limitations into the claims. Applicants are required to insert the ranges into the claims to define that which applicant intends as substantially pure. In the examination process, it is proper to use the specification to interpret what applicant intends by a word or phrase recited in the claims, but it

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is **not** proper to read these limitations appearing in the specification into the claim when these limitations are not recited in the claim. See *In re Paulsen*, 30 F. 3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994).

All claims which depend from an indefinite claim are also indefinite. *Ex parte Cordova*, 10 U.S.P.Q. 2d 1949, 1952 (P.T.O. Bd. App. 1989).

The examiner would like to cite US 2002/0019363 A1 as the closest prior art which teaches nucleoside analogues to treat flavivirus infections.

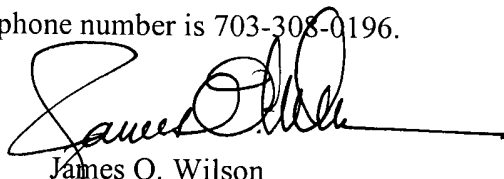
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C McIntosh whose telephone number is 703-308-9479. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Traviss C. McIntosh III
September 25, 2003


James O. Wilson
Supervisory Patent Examiner
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